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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,580	09/30/2003	Hassan Serhan	101896-696 (DEP5077)	9958

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EXAMINER

SWIGER III, JAMES L

ART UNIT	PAPER NUMBER
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3775

NOTIFICATION DATE	DELIVERY MODE
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04/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/675,580	Applicant(s) SERHAN ET AL.	
	Examiner JAMES L. SWIGER	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11-13, 15, 24 and 37-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-13, 15, 24 and 37-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/15/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 11-13, 15, 37, 24 rejected under 35 U.S.C. 103(a) as being unpatentable over Serhan et al. (US Publication 2004/0073213) hereafter Serhan in view of Trieu (US Publication 2004/0102774).

Serhan discloses a fusion device comprising a body (10, Fig. 1), having a major axis and a proximal portion (towards 30) and a distal portion (opposite) and a body having a conduit (61/63) that is substantially parallel to the major axis. Serhan further discloses a support portion (Fig. 5), that is configured to support vertebrae in a distracted position (see Abstract and figs. 1 and 2) and wherein the support also has a conduit (57) that connects to the conduit of the main body (see fig. 1). The two conduits are considered to be in fluid communication with one another (44/45) and the support further has at least one outlet (24). The distal portion of the body is has a height distinct from a width taken at a cross section (see shape in Fig. 5, depending on how you look at it, also see claim 5) which is capable of distracting vertebrae. This support can be rotated to distract the vertebrae (see figs. 1 and 2) along the major axis. The head has a particular shape, which may be considered as a cage because of its shape, and is capable of maintaining the natural angle of the distracted vertebrae (for example 0050).

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Serhan also discloses that a flowable material may be in the device (see par 0042) which may be of various materials such as polymers and morselized products (see 0070).

Serhan discloses the claimed invention except for where a conduit extends through the body itself, or where the body may selectively engage the support portion, or wherein the support portion may include a balloon. Trieu discloses a spinal stabilization device that has a conduit connecting a body to support portions extending throughout the conduit (52, Fig. 2), and a balloon (55) in addition to the support member. It is noted that a conduit portion may be selectively engage a support (for example 30) and become detached. Polymers may also flow through the balloon. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Serhan having at least a conduit extends through the body itself, or where the body may selectively engage the support portion, or wherein the support portion may include a balloon in view of Trieu have more flexibility and direct access to the surgical site when performing the surgical procedure.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Serhan in view of Trieu. Serhan in view of Trieu disclose the claimed invention, including that various components may be made of biocompatible materials, except for where a support could also be biodegradable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device out of biodegradable material, since it has been held to be within the general skill of a worker

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in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochschuler et al. (US Publication 2002/0058947) hereafter Hochschuler. Hochschuler discloses a device that may be used for intervertebral stabilization comprising a body (32) that has a major axis having a proximal and (30) distal portions (approx. 36), further having a conduit that extends (24, near 36) parallel to a major axis extending throughout the body. Hochschuler also discloses a selectively expandable balloon that is detachably connected to the distal portion of the body (see Figs. 25-28), that is fully capable of being positioned between vertebrae permitting fusion. While the balloon may be made of various materials including those that are impermeable and porous, Hochschuler does not specifically disclose a biodegradable polymer. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the balloon out of biodegradable or other low-weight polymers, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

Applicant's arguments, see arguments, filed 1/16/2009, with respect to the rejection(s) of claim(s) 1-6, 12-13, 15, 24, 37-40 have been fully considered and are

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persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the above references.

This action is also responsive to the telephone conference held on 1/23/2009.

Additionally, applicant's arguments with respect to claims 1-6, 12-13, 15, 24, 37-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on M-F, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L. SWIGER/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775